Statistical Analysis Plan

Study title: Pilot study of a transdiagnostic, emotion-focused group intervention for young adults with substance use disorders

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BIOSTATISTICAL ANALYSIS

Power: The proposed pilot study is the first, necessary step in obtaining preliminary data to justify future larger, randomized trials. Although we will test for statistical significance, the primary aim is to obtain usable feasibility and acceptability data, as well as to estimate the adjunctive intervention's effect size in order to conduct more adequately powered studies in the future. As such, a formal power analysis was not conducted *a priori*; however, the proposed N (50 subjects) is in line with other recent pilot RCTs examining the feasibility and preliminary efficacy of cognitive-behavioral group interventions for young adults⁶¹ and teens⁶² with SUD.

Preliminary analyses will describe the participants' demographic and clinical characteristics. Comparisons will be made using Mann-Whitney or chi-square tests to determine if the randomization provided a balanced sample and if participants who dropped out differ from those who did not. All analyses will be conducted using the SPSS and/or Stata statistical packages.

<u>Specific Aim 1:</u> We will use descriptive statistics to report satisfaction ratings with the UP intervention (total CSQ-8 score; *Hypothesis 1a*) and number of UP sessions attended. We will use chi-square tests to evaluate differences in the proportion of participants in each condition who drop out of treatment at the ARMS program during the study period (*Hypothesis 1b*).

Specific Aim 2: Analyses will be intention-to-treat, such that participants will be analyzed as part of their allocated group irrespective how much treatment was received. Continuous variables (OASIS, ODSIS, BSI, CSS, and Craving Scale scores, frequency of NSSI urges and episodes captured by the SITBI, quantity and frequency of substance use, percent days abstinence [PDA]) will be analyzed with generalized mixed effect modeling, which imputes missing values based on maximum likelihood estimates of missing parameters (*Hypotheses 2a, 2b, 2c, 2d, 2e*). Time-by-condition interactions will be analyzed to test the efficacy of the adjunctive intervention. Known confounding variables (e.g., age, gender) will be included as covariates in these analyses. Effect sizes between the two conditions will also be reported. Although we will test for statistical significance, as previously noted, the primary aim of this pilot study is to estimate the intervention's effect size before conducting larger, more adequately powered future studies.